Title: IRB Review Process—Initial Review
Standard Operating Policy: # 6
Department: Human Research Protection Program/Institutional Review Board
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Subject: Initial Review Process

Policy:
Federal regulations require that in conducting the initial review of proposed research, Institutional Review Boards obtain information in sufficient detail to make the determinations required under 45 CFR 46.111 (or 21 CFR 56.111 for FDA-regulated research) regarding risks, potential benefits, informed consent, and safeguards for human subjects.

LLNL investigators who conduct research involving human subjects are required to submit an application describing their proposed research to the LLNL IRB, in order to obtain prospective IRB review and approval or certification of exemption from IRB review prior to initiating any research activities. No intervention or interaction with human subjects in research, including recruitment, and no collection of data about or samples from human subjects may begin until an investigator's application to conduct human subjects research has received LLNL IRB approval, a certification of exemption, or letter indicating that the material is not research related.

The receipt of a complete protocol is the first step in IRB review. Deadlines, ancillary reviews, and signature requirements need to be carefully considered and planned in advance. At the time protocol materials are received, all documents will be examined for compliance with submission requirements. The IRB Office also will perform a preliminary review of the protocol and may question the Principal Investigator directly on any concern before the actual IRB review. The Investigator must respond to the comments before the protocol is distributed and reviewed by the IRB. To ensure a thorough and complete review, the Principal Investigator should include the following points in his/her IRB application:

1. The full protocol or a protocol summary.

2. The proposed informed consent documents.

3. The grant application, if the research has federal sponsorship.

4. Copies of the IRB approval letter(s) and consent form(s) from other institutions involved in the research (if the project is a collaboration between/among other institutions).

5. The sponsor/company protocol and Investigator Brochure (if one exists), if the study involves an investigational drug or device. Results of previous animal and human studies that are summarized in the Investigator's Brochure.

6. The recruitment materials, including advertisements intended to be seen or heard by potential participants (e.g., posters, e-mail, or radio/televisions advertisements).

7. The process for the selection of participants.

8. The necessary provisions to protect the privacy of participants.

9. The necessary provisions to maintain the confidentiality of data.

10. The additional safeguards to protect the rights and welfare of participants who are likely to be vulnerable to coercion and undue influence.

All IRB members will receive the same documents for full committee review. In cases of expedited review, the IRB Reviewer(s) will receive all documents for review. The regulations specify criteria for IRB review and approval (see *Standard Operating Procedure #11, Criteria for Approval*). IRB members must apply these criteria during the review process and have appropriate knowledge and understanding of the regulations.

A tool to assist IRB members in performing an in-depth and thorough review is the IRB Review Evaluation Form (i.e., checklist). The form is divided into sections, and each section addresses the specific criteria for IRB approval, as specified in the regulations. Additional space is provided so that IRB members can pose questions to investigators. This form also helps the IRB Office document comments, prepare minutes, and report the IRB findings back to the Principal Investigator after IRB review. In addition, the form is a quality-control mechanism that ensures reviewers have considered all of the regulatory and institutional criteria for review and approval; it encourages and provides a level of consistency in the IRB review process, and it serves as written documentation that the IRB review process occurred.

In addition, the comments gathered through e-mail correspondence shall also be included in the protocol file. This will include correspondence between the Principal Investigator and IRB staff members, as well as correspondence received and sent to the expedited reviewers in the case of expedited review.